March 28, 2025
VIA ECF
Hon. Philip M. Halpern
Southern District of New York
300 Quarropas St., Courtroom 520
White Plains, NY 10601

Re: *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.*, No. 7:20-cv-05502 (PMH) (S.D.N.Y.) – Joint Letter Regarding Discovery Dispute

Dear Judge Halpern:

Pursuant to L.R. § 37.2 and Rules 2(C) and 4(D) of Your Honor's Individual Practices Rules, Plaintiff Regeneron submits this letter jointly with the Novartis Defendants to respectfully request a conference to resolve a dispute concerning production of (1) Novartis's Patent Prosecution Guide and (2) documents from Patent and Trial Appeal Board (PTAB) proceeding IPR2021-00816. The parties are at an impasse, and their respective positions are below.[1] To the extent these issues remain unresolved, Regeneron seeks authorization to file a motion to compel.

Application granted. A discovery dispute conference is scheduled for May 7, 2025 at 3:30 p.m. to be held in the White Plains courthouse. The Clerk of Court is respectfully requested to terminate the pending letter-motions (Doc. 168, Doc. 169).

SO ORDERED.

Philip M. Halpern
United States District Judge

Dated: White Plains, New York
March 31, 2025

I. Novartis's Patent Prosecution Guide ("Guide")

Regeneron's Position: The Guide is responsive to I
Regeneron's *Walker Process* claims alleging that Novartis
material prior art and information from the Patent and
prosecution of the application that issued as U.S. Pat. 9,
Novartis recently produced a redacted Guide in place of the
produced in 2022, Novartis's privilege claim over the redacte

First, Novartis waived privilege over the Guide. After withholding the ***entire*** Guide as privileged since 2022 (Ex. 3, 11:2-12:1; Ex. 4, 5:23-6:4; Ex. 5 at 4), Novartis recently produced a redacted Guide and now contends it "contains both privileged and non-privileged material."

[1] The parties complied with the meet and confer obligation in advance of filing the letter.
[2] Regeneron raised this dispute in Case No. 1:20-cv-690 (NDNY), but it was never resolved.

Novartis has selectively redacted purportedly privileged portions, but left unredacted material that Novartis claimed for years also constituted legal advice. *Id.* The redactions appear in the same sections as unredacted text describing prosecution strategy, which concern the same subject matter and should in fairness be considered together. *Stolarik v. N.Y. Times*, 2019 WL 4565070, at *3 (S.D.N.Y. Sept. 20, 2019); *e.g.*, Ex. 2 at 4-8, 13-14 (highlighting unredacted text near redactions concerning "prosecution strategies"). Novartis's intentional and selective disclosure of portions of the Guide it previously claimed were privileged is a waiver as to the entire Guide. *Id.* at *2.

Indeed, Novartis has failed to distinguish the redacted portions from the unredacted portions. The unredacted portions, some of which are part of the same sentence as redacted portions, do not "merely describe" or "summarize" the law or common practices or "provide non-legal advice." *See, e.g.*, Ex. 2 at 4-8, 13-14. As such, it is not plausible that the redacted portions constitute legal advice, while the unredacted contents do not. Novartis's production of the vast majority of the Guide either confirms that none of the Guide is privileged, or that Novartis has waived privilege by selectively disclosing the contents of a privileged communication.

Second, despite claiming privilege over the Guide since 2022, Novartis also waived privilege by first serving a privilege log on March 10, 2025. *Gateguard v. Amazon.Com*, 2024 WL 3952145 (S.D.N.Y. Aug. 27, 2024). Its assertion that it logged the recently produced Guide in 2022 is incorrect as the logged documents have different dates.[3] Ex. G (PL(US)_2149); Ex. B.

Novartis's Position: The Guide contains both privileged and non-privileged material. Novartis has already produced the non-privileged portions, e.g., sections that merely describe what the law is, that summarize common practices and requirements of patent examiners, or that provide non-legal advice regarding note taking, or time- and cost-saving measures. *See, e.g.*, Ex. 2 at 20

[3] Novartis should be compelled to produce all versions of the Guide.

(advice on consideration of commercial justification for patent applications). Notably, Regeneron does not claim that any of the unredacted material is privileged. Rather, despite demanding for years that Novartis produce a less redacted copy of the Guide, Regeneron now appears to argue that privilege redactions are improper. But the redacted portions of the Guide constitute (1) "a communication between client and counsel" (2) "made for the purpose of . . . providing legal advice," (3) that "was intended to be and was in fact kept confidential." *In re Cnty. of Erie*, 473 F.3d 413, 419 (2d Cir. 2007). Production of this privileged material should not be compelled.

First, the Guide was drafted and edited by attorneys and patent agents in Novartis's Intellectual Property Practice Group ("IPPG") to assist other IPPG attorneys to obtain quality patents and to devise and implement prosecution strategies for the applications in their care. Ex. A, Declaration of Jennifer Chapman ("JC") ¶¶ 2–3.

Second, the redacted portions of the Guide are replete with legal advice from Novartis's in-house counsel and from external patent attorneys and agents regarding various topics, including prosecution strategies that may maximize the likelihood of issuance in various jurisdictions and litigation and invalidation risks. *Id.* ¶¶ 4–5. This advice is precisely the sort that the attorney-client privilege is designed to protect. *See, e.g.*, *In re Currency Conversion Antitrust Litig.*, 2010 U.S. Dist. LEXIS 117008, at *23–24 (S.D.N.Y. Nov. 3, 2010) (upholding attorney-client privilege over training materials covering topics "for which a corporation would choose to rely upon an attorney's advice" and where materials advised on issues that may "have legal consequences").

Third, the Guide was distributed only to the audience that it was intended to assist. Specifically, the authors of the Guide drafted it as a resource for the IPPG. Thus, the Guide was circulated internally to the IPPG—not companywide. JC ¶¶ 7–8. By circulating the Guide only to the limited group of Novartis professionals who the advice was intended to assist, Novartis

maintained the confidentiality of the Guide. *See Currency*, 2010 U.S. Dist. LEXIS 117008, at *17 (noting advice remains privileged when sent to those who share responsibility for subject matter).

Novartis has not waived privilege, and the case law Regeneron cites does not suggest otherwise.[4] Unlike in *Stolarik*, Novartis has not voluntarily produced privileged documents on the same topics redacted in the Guide. Nor has Novartis failed to provide a timely privilege log as in *Gateguard*. Novartis first logged the Guide in June 2022. Ex. G. Novartis logged the same version in March 2025 (Ex. B), reporting the Guide's "Release date" (Ex. 2) instead of the metadata date.

II. Production of Materials from IPR2021-00816

Regeneron's Position: Novartis should be compelled to produce confidential versions of its briefs and the PTAB's decisions from IPR2021-00816 ("IPR papers"), in which the PTAB invalidated the 631 Patent. The underlying confidential exhibits are already subject to the parties' cross-use agreement, and there is no basis for Novartis to withhold the remaining IPR papers.

The IPR papers are responsive to Regeneron's RFPs 39, 42, 45, 67, 89 (relationship with Genentech), 95 (631 Patent licensing), and 103. Ex. 1. Novartis does not dispute responsiveness to RFPs 39, 42, 45, and 67, but erroneously contends that the parties agreed those RFPs do not apply after July 17, 2020. Novartis also contends that the IPR papers are not relevant because Regeneron asserted in its IPR Petition that there was no "overlap of issues" with this case. But that statement is irrelevant because it was made before the IPR papers existed. Finally, Novartis asserts that the public versions of the IPR papers are sufficient. This is incorrect because the public versions redact highly relevant information, including Novartis statements concerning prior art relevant to Regeneron's *Walker Process* claim (Count 1). Ex. 6 at 25-27 (redacting Novartis

[4] Novartis did not intend to waive privilege in attempting to resolve a discovery dispute. If the Court finds Novartis did waive, Novartis would seek an order under Rule 502(d) allowing a claw back or limiting the scope of any waiver to the unredacted material already produced.

statements regarding prior art). The confidential IPR papers also include information relevant to Regeneron's antitrust claims generally, including Novartis statements regarding (1) its paid assistance to Genentech in launching Lucentis pre-filled syringe ("PFS") in the U.S. by licensing the 631 Patent, which rebuts Novartis's defense that it does not compete in the U.S. market; and (2) the importance of the PFS method of administration, which supports Regeneron's allegations that Novartis competes in a PFS antitrust market distinct from a vial market. Ex. 7 at 20 (redactions regarding physician preference for PFS over vial), 26-27 (redactions regarding Genentech license).

Novartis's Position: Novartis should not be compelled to produce unredacted versions of the IPR papers.[5] The redacted IPR papers are publicly available and the redacted statements are not responsive to any request that Regeneron timely served to Novartis.

In 2022, the parties conferred regarding a temporal scope for discovery and agreed to a June 19, 2020 cutoff for document discovery (with certain exceptions not at issue here). *See* Ex. D at 2; Ex. E at 4–5, Ex. F at 3. Regeneron filed its IPR petition on April 16, 2021, and thus the IPR papers are not within the agreed-upon temporal scope of RFPs 39, 42, 45, and 67. Presumably to get around this limitation, Regeneron for the first time in this letter argues that the IPR papers are responsive to RFPs 89 and 95, recent requests not subject to the prior agreement. To the extent the IPR papers contain unredacted statements regarding Novartis's relationship with Genentech (RFP 89) or the licensing of the '631 patent (RFP 95), those statements do not render the redacted (non-responsive) statements regarding prior art responsive to these RFPs. Finally, while RFP 103 seeks the IPR papers, Regeneron served the request well after the deadline for document discovery had passed (ECF No. 159) and the parties have never conferred in relation to this untimely request.

[5] Regeneron argued to the PTAB that there would be "no overlap of issues" between the IPR and this case when such a position supported institution of the IPR. *See* Ex. C at 7. In another about-face, it now seeks to obtain unredacted copies of the IPR papers.

Respectfully submitted,

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